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EXAMINER	
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3693	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/825,533	HUFFORD ET AL.	
	Examiner	Art Unit	
	MARTIN A. GOTTSCHALK	3693	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6,9,12,13,16,17,20-30,48-52 and 54-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6,9,12,13,16,17,20-30,48-52 and 54-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. Claims 4, 6, 9, 12, 13, 16, 17, 20-30, 48-52, and 54-63 are pending. Claims 4, 9, 12, 13, 16, 24, 26-29, 48-52, 54, and 56 are amended. Claims 58-63 are new. Claims 6, 17, 21, 22, 25, 30, 55, and 57 are as previously presented. Claims 20 and 23 are as per the original. Claims 1-3, 5, 7, 8, 10, 11, 14, 15, 18, 19, 31-47, and 53 are cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/24/2010 has been entered.

Response to Arguments

3. Applicant's arguments in the response filed 09/24/2010 have been fully considered but they are not persuasive. On pages 15 to 18 of the response, Applicant makes two related arguments that are applied to all of the independent claims (claims 4, 16, 24, and 48-52). The first argument concerns the "comparing" step of the claims. It is asserted in essence that the claimed benchmark parameter (e.g. the "compliance

threshold" of claim 4; the "prediction rule" of claim 16; or the "decision rule" of claim 24) which is compared to the same parameter as measured for individual subjects (to determine if a subject has complied satisfactorily) is not the same as the cited "challenge level" taught by the primary Stark reference. As stated for example on page 15 of the response, this is so, "because the 'challenge level' is an individualized protocol level that varies in response to a patient's performance during orthopedic rehabilitation," as opposed to being a "common benchmark to which measurements of subject compliance from each subject in a group of subject<s> participating in a current clinical trial are compared," which Applicant apparently feels is implicit in the recitations of the independent claims.

In response, the Examiner respectfully disagrees that the Stark reference as applied specifically to the recited language of the claims does not teach the features to which it is applied. As cited in the rejection for these claims, algorithms for assessing patient compliance based on historical patient protocol compliance data are produced by the system. So for instance, Stark col 11, lns 34-48 uses an algorithm to create a treatment protocol that could compare patient performance to a "goal" level of performance. The algorithm would have been generated from historical information (Stark: col 5, lns 12-29; col 7, lns 25-60; col 12, lns 18-26), and could include a component to measure compliance (e.g. Stark: Fig 11) which is also based on historical information (Stark: col 5, lns 26-29). The fact that Stark refers to individual patients, and not groups of patients in clinical trials, is remedied by the McAlindon reference. Thus a protocol of Stark,

including compliance information, could be applied to a group (i.e. a plurality of individual patients), such as a cohort of patients in a clinical trial.

The second argument is that modifying the "challenge level" of Stark to adapt it to a group of patients would render it unsatisfactory for its intended purpose. The Examiner respectfully disagrees and refers Applicant to the previous paragraph for the discussion of adapting the individual patient protocols of Stark to groups on patients in McAlindon.

4. On page 19, Applicant notes a typographical error associated with claim 12 and requests that the finality of the previous Office Action be rescinded because of it. The request is respectfully denied inasmuch as the error should not have led to any confusion as to the meaning of the rejection. The error was that reference to Drazen was carried over from an earlier office action instead of changing it to McAlindon. However, the substance of the rejection remained the same, namely that the Smith reference was brought in to modify the Stark reference to reject the claim, and was unaffected as to whether or not Drazen or McAlindon was applied.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 4, 6, 9, 13, 16, 17, 20-30, 48-52, and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stark et al (US Pat# 6,827,670, hereinafter, Stark) in view of McAlindon et al (US PG Pat# 7,251,609).

As per independent claim 16, Stark discloses a method of determining if action is needed regarding subject noncompliance (see below for application to a clinical trial), comprising the steps of:

(a) providing historical subject compliance data (col 5, ln 64 to col 6, ln 1; col 7, 57-65, i.e. "historic database" includes "patient compliance information." Note that any data taken from a current patient's treatment is incorporated into the historical database for future use; col 11, lns 40-48; Fig. 11, i.e. patient compliance data from the past 10 days is provided to the central computer. See below for wherein the historical compliance data is from a previous clinical trial),

wherein historical subject compliance data comprises,

data on timeliness of a data entry (Stark: col 11, lns 34-39, reads on “time of their completion”),

data on a ratio of completed assessments to expected assessments (Stark: col 11, lns 34-48; col 12, lns 18-34),

data on a subject's compliance with a medication regimen (Stark: col 4, lns 13-16, i.e. “biological manipulation”; claim 19, “drugs”),

data on a disease episode (Stark: col 11, lns 38-39),

or

data on a characteristic of a subject's disease state; (Stark: col 7, lns 34-36, reads on “historic outcomes.”);

(b) generating a predictive (Stark: col 8, lns 45-57, i.e. the system is designed for prediction) algorithm for predicting subject noncompliance (Stark: col 13, lns 38-39. Note the use of low "compliance track record" as an input to the algorithm which determines if or by how much to adjust the "challenge level," i.e. a subject who has complied poorly in the past would have this history taken into account with respect to future protocol adjustments. Note further that the Examiner considers the "challenge level" to be a type of "compliance threshold," as recited in claim 4) by quantitative analysis of the historical subject compliance data (Stark: col 12, lns 48-63; Fig 14, note the graphic representation which is a type of quantitative analysis.);

(c) translating the predictive algorithm into at least one prediction rule (Stark: col 9, ln 55 to col 10, ln 30; col 13, lns 6-16, i.e. the Examiner considers that the algorithm is translated it into a rule such as, "If the patient has achieved near 100% performance, then the challenge level of the protocol should be increased." See below for application to clinical trials feature: and "removing" feature in claims 4 and 24);

(d) obtaining subject compliance information (Stark: col 11, lns 40-48; Fig. 11, i.e. compliance data is obtained from the patient; col 13, lns 2-5, reads on, "...level of average compliance." See below for application to clinical trials) comprising

using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain said subject compliance information;

(e) comparing the subject compliance information to the at least one prediction rule to determine if action is needed (Stark: col 5, lns 34-36; col 9, ln 55 to col 10, ln 30; col 12, lns 18-39; col 13, lns 2-5);

and

(f) prompting action if the step of comparing indicates that action is needed (Stark: : col 9, ln 55 to col 10, ln 30; col 13, lns 13-16, reads on "…algorithm increases the challenge level…").

Steps (a) [previous]; and (c) and (d) [current] above distinguish between previous and current clinical trials as follows:

(a) providing historical subject compliance data from a previous clinical trial;

(c) translating the at least one predictive algorithm into at least one prediction rule for use during the current clinical trial;

and

(d) obtaining subject compliance information from a subject participating in said current clinical trial.

Stark suggests additional uses of the data generated by the system (Stark: col 12, lns 40-42), but fails to explicitly teach use of the system in clinical trials, as recited in the features added by amendment of

wherein said current clinical trial comprises a group of subjects participating in said current clinical trial;

and wherein in the obtaining step (d) above, compliance information is obtained

from each said subject in said group of subjects;

and wherein the comparing step (e) above is done so as to compare compliance information

from said each subject in said group of subjects

to the prediction rule to determine if action is needed

for said each subject in said group of subjects.

However, these features are well known as taught by McAlindon. McAlindon teaches an on-line system of recruiting for (McAlindon: abstract) and conducting clinical trials (McAlindon: col 2, lns 44-54), and is concerned with monitoring patient compliance with the clinical trial protocol (McAlindon: col 23, lns 25-56; col 24, lns 35-50; col 25, lns 49-62). The Examiner notes that clinical trials generally have a group of subjects participating in them, and that the teachings of Stark provided above could be applied to each subject in a group of subjects participating in a clinical trial.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Stark concerning the use of historical patient compliance information with the clinical trials system of McAlindon, in order to use the internet to improve the efficiency in conducting clinical trials, for example by improving compliance with a trial protocol (McAlindon: col 1, lns 50-56; col 2, lns 27-40), and by leveraging the expertise of the physicians and treatment professionals involved (McAlindon: col 1, lns 58-62; Stark: col 2, lns 14-18).

As per independent claims 4, 24, and 48-52; and **dependent claims** 6, 9, 25, 26, and

exemplary claim 17, Stark discloses the method of predicting subject noncompliance of claim 16,

NOTE: Independent claims 4, 24, and 49-52 recite the following feature added by amendment to feature (e) of exemplary independent claim 16, not present in claim 16:

wherein said action comprises (see McAlindon reference below for removal from the clinical trial)

prompting said subject participating in said current clinical trial to view said portable electronic device (Stark: col 6, lns 14-21),

alerting clinical staff to contact said subject participating in said current clinical trial regarding compliance with said clinical trial (Stark: col 9, lns 39-48),

providing compliance feedback to said subject participating in said current clinical trial to encourage continued compliance with said current clinical trial (Stark: col 9, ln 39 to col 10, ln 24, reads on "provide a psychological boost to the patient"),

providing compliance feedback to said subject participating in said current clinical to remediate poor compliance with said current clinical trial (Stark: col 9, lns 39-67),

providing a report on the compliance of said subject participating in said current clinical to said clinical staff or a clinical trial sponsor, (Stark: col 9, lns 39-48; Fig 11; col 11, lns 24-49; col 11, lns 2-7)

or

training said clinical staff in the monitoring and correcting of subject compliance (Stark: col 8, lns 57-63).

wherein said step of providing further comprises

providing historical protocol data (Stark: col 5, lns 2-4; Fig 9, note that item 107 is labeled “Receive a Protocol” and is connected by arrow 108 coming from the box labeled “Historic Protocols…”)

and

wherein said step of generating further comprises

quantitative analysis of the historical protocol data (Stark: col 7, lns 41-43),

NOTE: In addition to dependent claims 9, 17, and 25, independent claims 48 and 50 also have the following feature added by amendment:

wherein historical protocol data comprises

a question posed to a subject (Stark: col 8, lns 30-41; col 14, lns 28-37,i.e. the Examiner considers that, "...prior patient…demographic information…" was obtained by posing relevant demographic questions to the historical patients.),

the frequency of prompting of a subject during the day or week,

the amount of time allotted for a subject to respond to a question (see below for further the "condition mandating removal" feature),

Stark fails to disclose

wherein historic protocol data comprises a condition mandating removal of a subject from data analysis or from participation in a clinical trial

and

wherein said action comprises

removing all or part of the data from said subject participating in said current clinical trial from data analysis,

removing all or part of the data from said subject participating in said current clinical trial from a report,

or

removing said subject participating in said current clinical trial from said current clinical trial,

However, this feature is well known as disclosed by McAlindon (McAlindon: col 23, 52-55).

The motivation to combine the teachings of Stark and McAlindon is the same as provided above for claim 16.

As per claim 30, Stark discloses the method of predicting subject noncompliance of claim 24, wherein the step of obtaining comprises

the use of a portable electronic device capable of displaying information and receiving and storing input from a user (Stark: col 8, lns 12-30).

As per claims 20-22, Stark discloses the method of predicting subject noncompliance of claim 16 and 20 (for 21 and 22), further comprising the step of

(claim 20) creating an evaluability database adapted to store data related to subject compliance (Stark: col 8, lns 57-63; col 7, ln 63 to col 8, ln 3);

and

(claim 21) providing access to the evaluability database to a sponsor to allow the sponsor to make a determination regarding a subject based on data from the evaluability database (Stark: col 8, lns 57-63; col 7, ln 63 to col 8, ln 3); and

(claim 22) evaluability database is tailored to a condition affecting the subject (For all three claims, Stark: col 8, lns 57-63, whereby sponsor reads on "treatment professional", and the cited "treatment protocol" is considered to be tailored to a condition affecting the patient. See also col 7, ln 63 to col 8, ln 3).

As per claims 13 and exemplary claim 23, Stark discloses the method of determining subject noncompliance of claim 16, wherein the step of providing

> employs at least one database containing the historical subject compliance data (Stark: Fig 9, item 36 and box labeled "Historic Protocols…" which is shown to be receiving input from item 40; Fig 10, item 36).

As per claims 27 and 28, Stark discloses the method of enhancing subject compliance of claim 24, wherein the corrective action further comprises

(claim 27) reducing (Stark: col 9, ln 67 to col 10, ln 21);

and

(claim 28) increasing

a number of occurrences of the step of obtaining subject compliance information (For both claims, Stark: col 9, ln 67 to col 10, ln 21. The Examiner considers the "…replicate count…" to be a form of compliance information, and notes it is increased following detection that the previous "…effort or angle objective…" was not being achieved. Since the number of occurrences of a replicate would be increased, so would obtaining this particular form of compliance information. Likewise, if the patient is "…satisfying ahead of schedule, the treatment goal…", logically, the algorithm would move in the opposite direction from the previous example and "…modify the treatment protocol…" such that the "protocol goals may be raised to more challenging levels…". In this scenario, the patient would require an increase in the required effort, and following the logic of the former example, the number of replicates required to comply with the treatment protocol would be reduced.).

As per claim 29, Stark discloses the method of enhancing subject compliance of claim 24, wherein the corrective action further comprises giving a reward (Stark: col 10, lns

13-23, reads on "…psychological boost…").

As per claims 54-57, Stark teaches the method of claims 4, 16, or 24, wherein said historical subject compliance data further comprises

data on whether a subject had a relationship with a doctor or other medical professional (Stark: col 5, reads on "attending treatment professional"),

data on a number or percent of prompts not replied to by a subject,

data on a subject's sleep/wake cycle,

data on whether a subject had a bowel movement,

data on an amount of time a portable electronic device is in suspend mode,

data on a subject's gender (Stark: col 8, lns 30-41; col 14, lns 28-37,i.e. "...patient…demographic information…").,

or

data on a subject's location (Stark: col 8, lns 30-41; col 14, lns 28-37,i.e. "...patient...demographic information...").

As per claims 58 and 61, Stark teaches the method of claim 4, wherein said compliance threshold remains unchanged throughout said current clinical trial (Stark: col 9, ln 55 to col 10, ln 30; col 13, lns 6-16, i.e. the Examiner considers that the algorithm might produce a compliance threshold such as, "If the patient has achieved near 100% performance, then the challenge level of the protocol should be increased" which could remain in effect throughout the trial.

As per claims 59 and 62, Stark teaches the method of claim 16, wherein said prediction rule is generated without data from activities of said current clinical trial (Stark: col 9, ln 55 to col 10, ln 30; col 13, lns 6-16, i.e. the Examiner considers that the algorithm is translated it into a rule such as, "If the patient has achieved near 100% performance, then the challenge level of the protocol should be increased." Note that the "near 100%" could be generated from historical information, independent of the current trial.).

As per claims 60 and 63, Stark teaches the method of claim 24, wherein said decision rule is generated without data from activities of said current clinical trial (Stark: col 9, ln 55 to col 10, ln 30; col 13, lns 6-16, i.e. the Examiner considers that the algorithm might generate a rule such as, "If the patient has achieved near 100% performance, then the challenge level of the protocol should be increased." Note that the "near 100%" could be generated from historical information, independent of the current trial.).

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stark in view of McAlindon as applied to claim 24 above, and further in view of Smith (Smith, G., "Statistical Reasoning." Third edition. Ch. 15, pgs. 619-667. Allyn and Bacon, a Division of Simon and Schuster, Inc., Needham Heights, MA. 1991, hereinafter Smith.).

As per claim 12, Stark suggests the use of statistical analysis and techniques (Stark: col 7, lns 41-48) but fails to explicitly disclose the specific statistical techniques of claim 12.

However, these features are well known in the art as evidenced by the teachings of Smith who discloses the method of determining subject compliance of claim 24, wherein

the step of generating employs at least one of the group of

multiple linear regression (Smith: Ch 15.)

discriminant function analysis,

logistic regression,

neural networks,

classification trees

and

regression trees.

It would have been obvious at the time of the invention to one of ordinary skill in the art to incorporate the teachings of Smith within the method of Stark with the motivation of isolating the separate effect of each of several independent variables on a single dependent variable (Smith: pg 620, second paragraph).

Conclusion

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARTIN A. GOTTSCHALK whose telephone number is (571)272-7030. The examiner can normally be reached on Mon - Fri 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James A. Kramer can be reached on (571) 272-6783. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. A. G./
Examiner, Art Unit 3693

/James A. Kramer/
Supervisory Patent Examiner, Art Unit 3693